SMaRT oncology-2: a two arm parallel group randomised controlled trial to determine the effectiveness and cost-effectiveness of adding a complex intervention for major depressive disorder ('Depression Care for People with Cancer') to usual care, compared to usual care alone in cancer patients

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
13/05/2008		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
30/05/2008		[X] Results		
<b>Last Edited</b> 04/04/2022	Condition category  Mental and Behavioural Disorders	[] Individual participant data		

# Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-treating-depression-people-with-cancer-smart-oncology-2

# **Contact information**

# Type(s)

Scientific

#### Contact name

**Prof Michael Sharpe** 

#### Contact details

School of Molecular and Clinical Medicine
The University of Edinburgh
Kennedy Tower
Royal Edinburgh Hospital
Morningside Park
Edinburgh
United Kingdom

EH10 5HF +44 (0)131 537 6672 michael.sharpe@ed.ac.uk

# Additional identifiers

Protocol serial number

v1.1 12/05/08

# Study information

### Scientific Title

SMaRT oncology-2: a two arm parallel group randomised controlled trial to determine the effectiveness and cost-effectiveness of adding a complex intervention for major depressive disorder ('Depression Care for People with Cancer') to usual care, compared to usual care alone in cancer patients

## Acronym

SMaRT (Symptom Management Research Trials)

# Study objectives

- 1. 'Depression Care for People with Cancer' as a supplement to usual care will be more effective than usual care alone in achieving a 50% reduction in baseline 20-item depression score from the Symptoms Checklist (SCL-20D) at 24 weeks
- 2. 'Depression Care for People with Cancer' as a supplement to usual care will cost more than usual care alone but will be more cost effective in achieving improvements in patients depression and quality of life

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Scotland A research ethics committee, 31/03/2008, ref: 08/MRE00/23

# Study design

Multicentre randomised controlled two-arm parallel-group trial

# Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Depression in patients with cancer

#### **Interventions**

Patients will be randomised to receive:

- 1. Usual care, or
- 2. Usual care plus 'Depression Care for People with Cancer'

Usual care arm:

The usual care of depression from the patient's GP or oncologist (this is routine care and won't be influenced by the researchers)

Usual care plus 'Depression Care for People with Cancer' arm:

In addition to usual care as above a complex intervention for depression delivered by a specially trained cancer nurse under the supervision of a psychiatrist, a maximum of 10 treatment sessions delivered over 16 weeks followed by monthly monitoring of progress until 12 months. The intervention comprises education about depression and its treatments (including antidepressant medication, which would be prescribed by the GP if the patient wishes to take it, and behavioural activation) and problem solving treatment.

## Intervention Type

Other

#### **Phase**

**Not Specified** 

## Primary outcome(s)

Treatment response, measured at 24 week outcome data collection, defined as a reduction of 50% or more in the patients baseline SCL-20D score

# Key secondary outcome(s))

- 1. Remission of major depressive disorder, defined as an SCL-20D score of less than 0.75 at each of 24, 36 and 48 weeks (higher than in primary care trials, to allow for cancer-related somatic symptoms)
- 2. Depression severity, defined for each patient as the average of their SCL-20D score at 24, 36 and 48 weeks

#### Completion date

01/06/2011

# **Eligibility**

### Key inclusion criteria

Patients must:

- 1. Have a diagnosis of cancer, with active disease within the last five years
- 2. Be aged 18 or over, either sex
- 3. Be attending a specialist oncology clinic
- 4. Have a predicted survival, estimated by their cancer specialist, of twelve months or more
- 5. Have symptoms that meet Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria for major depressive disorder (MDD), with symptoms of the current major depressive episode (MDE) present for four weeks or more using the inclusive approach to diagnosis

## Participant type(s)

**Patient** 

### Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

All

## Total final enrolment

500

## Key exclusion criteria

- 1. Patients are unable to provide informed consent to participate
- 2. The episode of depression is chronic (defined as a history of continuous depression for at least two years)
- 3. They are judged to require urgent psychiatric care
- 4. They are receiving active psychiatric or psychological treatment from specialist mental health services
- 5. They have cognitive impairment or communication difficulties (including inability to adequately understand verbal explanations or written information in English) which are incompatible with the intervention
- 6. They have known cerebral metastases
- 7. They are unable to attend regularly for treatment sessions
- 8. The intervention is judged to be inappropriate due to a medical condition which requires alternative treatment
- 9. The intervention is judged to be inappropriate due to a psychiatric condition which requires alternative treatment (psychotic illness, bipolar affective disorder, obsessive compulsive disorder, substance abuse or dependence)
- 10. Their participation in the trial is judged to be inappropriate on other clinical grounds

N.B. Patients receiving active cancer treatments will not be excluded unless they fulfil one or more of the exclusion criteria listed above.

#### Date of first enrolment

15/05/2008

### Date of final enrolment

01/06/2011

# Locations

### Countries of recruitment

United Kingdom

Scotland

## Study participating centre

## The University of Edinburgh

Edinburgh United Kingdom EH10 5HF

# Sponsor information

## Organisation

University of Edinburgh

## **ROR**

https://ror.org/01nrxwf90

## Organisation

NHS Lothian - University Hospitals Division (UK)

# Funder(s)

# Funder type

Charity

#### **Funder Name**

Cancer Research UK (CRUK) (UK)

## Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

## **Funding Body Type**

Private sector organisation

# **Funding Body Subtype**

Other non-profit organizations

#### Location

United Kingdom

# **Results and Publications**

# Individual participant data (IPD) sharing plan

Not provided at time of registration

# IPD sharing plan summary

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/09/2014		Yes	No
Results article	results	01/12/2015		Yes	No
Protocol article	protocol	30/03/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results		(	04/04/2022	No	Yes